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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,341	10/25/2001	Bradley Stuart Galer	1203-01	3845

7590 02/27/2004

IP Department
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36th Floor
1600 Market Street
Philadelphia, PA 19103

EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary	Application No.	Applicant(s)	
	10/045,341	GALER, BRADLEY STUART	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 8-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, response, and petition for extension of time, all received on 05 December 2003.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3, 6, 8, 9, 11, and 12 under 35 U.S.C. 102(b) as being clearly anticipated by Hind is withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3, 6, 8, 9, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable over Hind is withdrawn.

The rejection of Claim 3 under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.* is rendered moot with the cancellation of that claim.

The rejection of Claims 1 and 8-15 under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.* is maintained.

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.*

The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects (See Column 3, Lines 1-17 and 29-36). In the disclosed compositions, lidocaine is present in amounts of about 1 to 25% by weight (See Column 3, Lines 55-65). Included in the disclosure are details of a study in which patches containing 5% lidocaine as well as other excipients are administered to patients. The patches are applied to areas of greatest pain, up to 12 hours (See Column 15, Lines 11-39).

Hind does not indicate that the disclosed compositions and methods can be used to treat pain from the group consisting of myofascial pains, fibromyalgia, bursitis, costrochondritis, repetitive motion injuries, carpal tunnel syndrome, and nociceptive pain.

The Rolf *et al.* patent teaches an analgesic adhesive patch that can be used to treat arthritis, backache, muscular aches, and strains. Lidocaine is listed among the active ingredients suitable for use in the disclosed patch (See Claims 1 and 3).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hind and Rolf *et al.* into the objects of the instant application. The teachings of Hind provide for topical lidocaine compositions and methods to treat pain in a way that produces analgesia without causing anesthesia. The teachings of Rolf *et al.* disclose that, in one embodiment, an analgesic patch comprising lidocaine can be used in the treatment of pain caused by arthritis, backache, muscular aches, and strains, which are all known to be various types of nociceptive pain. It is the position of the examiner that one of ordinary skill in the art, at

the time the claimed invention was made, would be observe the structural similarity of the compositions disclosed in the prior art references, and would thus be motivated to use the compositions and methods of treatment of Hind to relieve pain stemming from the conditions described in Rolf *et al.* One of ordinary skill in the art would have a reasonable expectation of success that the compositions and methods of the combined disclosure of the prior art would allow for the use a patch comprising lidocaine in a concentration that induces analgesia, rather than anesthesia, for the treatment of both nociceptive pain and neuropathic pain.

Although the Hind patent discloses that lidocaine formulations may be applied for not more than about 24 hours (See Column 3, Line 66 to Column 4, Line 10), the examiner still reads an overlap in ranges between this disclosure and the limitation of administration for at least 24 hours, as cited in Claims 16 and 17.

Thus, the claimed invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 05 December 2003 have been fully considered but they are not found to be entirely persuasive.

The applicants have acknowledged that the disclosure of the Hind patent teaches the relief of pain by the use of lidocaine at concentrations that achieve analgesia without inducing anesthesia. However, the applicants have not acknowledged significant disclosures in Hind, particularly the concept that in the aim of achieving analgesia without inducing anesthesia, concentrations of lidocaine are not restricted only to the range of 4%-6%. The Hind patent

discloses that the concentration in plasters usually range from about 2-10% (See Column 3, Lines 55-65).

Furthermore, the examiner disagrees with the applicant's characterization of the nature of the invention of Rolf *et al.* The examiner would like to re-emphasize that the invention as claimed is an analgesic patch, which may include lidocaine as an active ingredient (See Claims 1, 3, 5, and 12). That the example cited by the applicant contains 8% lidocaine and still provides analgesic relief of pain, according to the language of the claims, would only, in the view of the examiner, reinforce the disclosure of the Hind patent.

The examiner would like to clarify his previous statement concerning the differences between neuropathic and non-neuropathic pain. The examiner did not intend to trivialize the difference between the two categories of pain. What the examiner intended was to state that by the collective disclosure of the prior art, it is known that by using lidocaine patches in proper concentrations, the analgesic relief of neuropathic pain and non-neuropathic pain can be achieved without inducing analgesia in a patient.

As such, the pending claims remain obvious in view of the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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